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Original Article

Consensus Validated List of Potentially Inappropriate Medication for the Elderly and Their Prevalence in South Korea☆

CME

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SUMMARY

Background: The aims of this study were to generate a comprehensive potentially inappropriate medication (PIM) list applicable for Korean elderly based on the international PIM lists (Beers, Screening Tool for Older Person's Prescriptions, and PRISCUS), and to determine the PIM prevalence rate in the elderly who utilized long-term care services.

Methods: We generated a list of drug ingredients included in all the three criteria, and also the current Korean national formulary list. Twenty-six drug ingredients belonging to seven drug classes were finally selected. A two-round Delphi survey consisting of 20 experts was conducted to make a consensus on the PIM criteria applicable to Korean elderly. Individual questions regarding PIM criteria were answered using a 5-point Likert scale. The PIM prevalence rate in elderly was analyzed using the National Health Insurance claims data and the Long-term Care Benefit claims data over a 6-month period (from July 2011 to December 2011).

Results: All 26 drug ingredients were determined to be PIMs for Korean elderly. The prevalence rate of PIM in elderly under long-term care was 41.4% (98,158/237,285 individuals). Benzodiazepines were the most prevalent PIM drug class (28.9%), followed by first generation antihistamines (26.9%). The use of nonsteroidal anti-inflammatory drugs and tricyclic antidepressants were 9.3% and 6.4% of total individuals, respectively.

Conclusion: The comprehensive PIM list may be helpful for clinical practitioners to optimize drug choices for their elderly patients. A relatively high PIM prevalence in the elderly suggests that efficient strategies should be designed to reduce PIM in elderly populations in long-term care settings.

1. Introduction

Inappropriate prescribing in the elderly is associated with negative outcomes including adverse drug events, increased hospitalization, and resource utilization[1–4]. Accordingly, avoiding inappropriate drug use is an important and effective strategy in reducing medication-related problems and reducing health care costs[5]. Several explicit criteria to screen potentially inappropriate medication (PIM) use in the elderly were used to evaluate inappropriate drug use status. Beers' criteria developed in the United States is the most frequently used[6], but concerns about the generalizability to other populations are increasing[7]. Thus, other criteria such as the Canadian criteria[8], Screening Tool for Older Person's Prescriptions (STOPP), and PRISCUS (Latin for old and venerable elderly) have been generated to apply to other regions. A new set of explicit criteria called STOPP was validated in Ireland and Britain and has been used in other European countries[9], and the PRISCUS list was specifically designed for its applicability in Germany[10]. We recognize the necessities of localized explicit criteria that reflect a country- or region-specific health care system, circumstances, cultures, drug market (especially reimbursement policy), and practice patterns. In Korea, Beers' criteria or STOPP criteria have been used in medicinal and pharmacological researches for identifying PIM[11–13], but they have not been verified

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for their applicability of foreign country-based PIM criteria to Korean settings yet.

Recently, the importance of medication use management in the elderly has been magnified since national long-term care services for the elderly were incorporated into the National Health Insurance (NHI) scheme since July 2008 in Korea. It is well known how important medication management in the elderly population at a higher risk of adverse drug events is. As one of the medication management strategies, reduction of PIM prevalence is crucial. In this regard, the generation of explicit criteria to evaluate PIM use in elderly should come first.

The aims of this study were to generate a comprehensive PIM list applicable for Korean elderly based on the three international PIM lists (Beers, STOPP, and PRISCUS), and to determine PIM prevalence rates in the elderly who utilized long-term care services.

2. Materials and Methods

2.1. Study design: A Delphi survey

To generate a PIM list specifically applicable to Korean elderly, two-rounds Delphi surveys with a number of questions were undertaken from July 9, 2013 to August 13, 2013. The Delphi method, as an expert consensus process, provides a systematic way to converge the expertise of people working in a particular area and gives guidance that is readily applicable to a particular context[14]. Three international PIM lists (Beers 2012 version, STOPP 2008 version, and PRISCUS 2010 version) often used worldwide, were used for drafting a PIM list for the Delphi survey in this study. Pharmacist researchers extracted a total of 31 intersectional drug ingredients which were included in all the three published PIM criteria as the above mentioned. Among them, five drug ingredients (doxepin, oxazepam, thioridazine, trimipramine, and zaleplon) which were not included in the current Korean national drug formulary list were excluded (Figure 1). Finally, 26 ingredients from seven drug classes were selected as PIM candidates (Table 1). Delphi panel experts were asked to rate their agreement levels on the inclusion of those 26 ingredients individually in the PIM list for Korean elderly with given clinical conditions/diseases. Rating scores were given according to a 5-point Likert scale: 1 = strongly agreed; 2 = agreed; 3 = equivocal; 4 = disagreed; and 5 = strongly disagreed. They were allowed to answer "unable to decide" if it was too difficult to rate a score. They were also asked to describe the reasons for their ratings, if possible. Survey questionnaires were collected via e-mail from the panel participants for two sequential rounds. A summary of ratings by panelists was fed back to all the panel participants after Round 1. Panel members were allowed to change their first ratings in Round 2. This process resulted in a list of statements that had substantial consensus in its ratings.

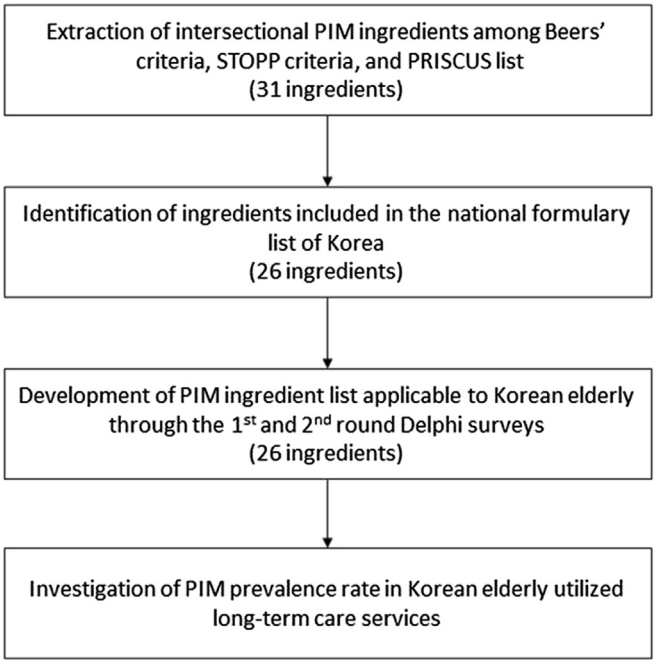

Figure 1. Flow chart of the study. PIM = potentially inappropriate medication; STOPP = Screening Tool for Older Person's Prescriptions.

2.2. Delphi participants

A total of 20 panel experts were invited to participate and complete the survey questionnaires in both Rounds 1 and 2. The panel size was a convenient sample number that was likely to yield stable results in this study. With a Delphi method, participants act as a panel of experts making private and independent ratings of agreement with a series of statements[15]. Expert panel participants in this study consisted of 14 physicians and six pharmacists who had experience in a wide range of specialties across the internal medicine, mental health, neurology, gerontology, preventive medicine, urology, family medicine, rheumatology, and clinical pharmacy fields, and who have been working in general hospitals or universities as clinical practitioners and/or researchers (Table 2).

2.3. Consensus validation of localized PIM list

After Round 2 was completed, the survey results were presented as mean scores of agreement levels for individual questions which were reported by 20 panel participants. A mean score of 3.0 was used as the cut-off point to be agreed on, including the drug in the localized PIM list for Korean elderly. Any items > 3.0 points were not eligible for the localized PIM list.

2.4. Data sources and data analysis

The NHI claims data and Long-term Care Benefit claims data were used to identify PIM exposure in the elderly. The administrative NHI claims data included information on patients' demographics (sex, age), clinical conditions (disease diagnosis ICD-10 codes), health care service utilization including inpatient and outpatient settings, drug prescriptions, and health care

Table 1
Drugs included in the national formulary list and listed as potentially inappropriate medication for elderly in the Beers, STOPP, and PRISCUS criteria.

Class of drug ingredients	Name of drug ingredients	No. of ingredients
TCAs	Amitriptyline, clomipramine, imipramine	3
Benzodiazepines	• Short- & intermediate-acting: alprazolam, clorazepam, triazolam • Long-acting: chlorazepate, chlordiazepoxide, diazepam, flurazepam	7
Neuroleptic drugs	Perphenazine, clozapine, haloperidol, olanzapine	4
1st generation antihistamines	Chlorpheniramine, clemastine, doxylamine, triprolidine	4
Antimuscarinic drugs	Oxybutynin	1
NSAIDs	Indomethacin, piroxicam, ketoprofen, meloxicam	4
Alpha-blockers	Prazosin, doxazosin, terazosin	3
Total		26

NSAIDs = nonsteroidal anti-inflammatory drugs; STOPP = Screening Tool for Older Person's Prescriptions; TCAs = tricyclic antidepressants.

Table 2
Specialty of Delphi Panel survey participants.

Specialty	No. of participants
Internal medicine	4
Mental health	2
Neurology	1
Gerontology	2
Preventive medicine	2
Urology	1
Family medicine	1
Rheumatology	1
Clinical pharmacy	6
Total	20

expenditures, and the Long-term Care Benefit claims data included information on patients' daily living activities and long-term care service utilization. Elderly patients who were aged ≥ 65 years and utilized long-term care services at either a nursing facility or home were enrolled to investigate PIM prevalence for the 6-month period (from July 1, 2013 to December 31, 2011). Based on the PIM list validated by the two-rounds Delphi panel survey the above mentioned overall PIM prevalence rate and prevalence per drug class were analyzed. Clinical conditions designated on the PIM criteria were determined using ICD-10 disease codes reported on the NHI claims data. SAS version 9.2 (SAS Institute Inc. Cary, NC) was used for data analysis. This study was approved by the Institutional Review Board of the NHI service (No. 2013-03).

3. Results

3.1. Consensus result

The mean scores for individual questionnaire items that 20 panel participants answered in Rounds 1 and 2 are shown in Tables 3 and 4. All 26 drug ingredients in a given disease or clinical condition listed as PIM candidates received < 3.0 point mean score and resulted in inclusion in the localized PIM list for Korean elderly.

3.2. Prevalence of PIM

The overall prevalence of at least one PIM was 41.4% (98,158 individuals) among a total of 237,285 elderly individuals who utilized long-term care services during a 6-month period. Benzodiazepines were the highest prevalent drug class which 28.9% of elderly individuals used, followed by first generation antihistamines used in 26.9% of individuals. Nonsteroidal anti-inflammatory drugs and tricyclic antidepressants were used in 9.3% and 6.4% of individuals, respectively (Figure 2).

4. Discussion

4.1. Consensus validation for PIM list

This study is the first attempt to elicit a localized list of explicit criteria for identifying PIM use, together with clinical conditions in the Korean elderly population, through a consensus validation process in which experts in the field of geriatric medications participated in. To set explicit criteria is important to identify PIMs involving potential risks of adverse drug events that outweigh its clinical benefit, and to design effective strategies to minimize those risks. There are very useful explicit criteria to identify PIMs which were developed in North America and European countries[16], but they have not been validated for Asian populations. More optimized criteria for Korean elderly is needed to precisely figure out PIM exposures at a higher risk in local populations. In this regard, the localized PIM list generated in this study which was consensus validated by Delphi survey will accelerate further discussions about

Table 3
Panel survey results: tricyclic antidepressants, benzodiazepines, and neuroleptic drugs.

Drug class	Ingredient	PIM criteria (disease/clinical condition) B = Beers' criteria S = STOPP criteria	Panel survey result (mean score)	
			Round 1	Round 2
TCAs	Amitriptyline, Clomipramine, Imipramine	Dementia (S), Dementia & cognitive/mental impairment (B)	1.95	1.95
		Glaucoma (S)	1.75	1.65
		Cardiac conductive abnormalities (S)	2.20	2.30
		Constipation (S) Chronic constipation (B)	2.25	2.30
		TCAs with an opiate or calcium channel blocker (S)	2.25	2.35
		TCAs with prostatism or prior history of urinary retention (S)	1.70	1.60
		Syncope or fainting (B)	1.70	1.60
		Delirium (B)	1.50	1.50
		A history of falls or fractures (B)	1.90	1.90
Benzodiazepines	(short- & intermediate-acting) Alprazolam, Clorazepam, Triazolam, (long-acting) Chlorazepate, Chlordiazepoxide, Diazepam, Flurazepam	Long-term (i.e., >1 mo), long-acting benzodiazepines with long-acting metabolites (S)	1.70	1.75
		Drugs that adversely affect those prone to falls (≥1 fall in past 3 mo) (S) A history of falls or fractures (B)	1.70	1.65
		Delirium (B)	1.95	1.95
		Dementia & cognitive/mental impairment (B)	1.84	1.85
Neuroleptic drugs	Perphenazine, Clozapine, Haloperidol, Olanzapine	Long-term (i.e. >1 mo) neuroleptics as long-term hypnotics (S)	2.05	2.10
		Long-term neuroleptics (>1 mo) in those with parkinsonism (S) Parkinson's disease (B)	1.74	1.85
		Drugs that adversely affect those prone to falls (≥1 fall in past 3 mo) (S) A history of falls or fractures (B)	1.95	1.95
		Syncope or fainting (B)	1.95	1.90
		Delirium (B)	2.60	2.65
		Dementia & cognitive/mental impairment (B)	2.13	2.25
		Chronic constipation (B)	2.40	2.35

PIM = potentially inappropriate medication; STOPP = Screening Tool for Older Person's Prescriptions; TCAs = tricyclic antidepressants.

Table 4
Panel survey results: first generation antihistamines, antimuscarinic drugs, nonsteroidal anti-inflammatories, and alpha-blockers.

Drug class	Ingredient	PIM criteria (disease/clinical condition) B = Beers' criteria S = STOPP criteria	Panel survey result (mean score)	
			Round 1	Round 2
1st generation antihistamines	Chlorpheniramine, Clemastine, Doxylamine, Triprolidine	Prolonged use (>1 wk) of first generation antihistamines i.e., diphenydramine, chlorpheniramine, cyclizine, promethazine (S)	1.68	1.68
		Drugs that adversely affect those prone to falls (≥1 fall in past 3 mo) (S)	2.00	2.00
		Chronic constipation (B)	2.37	2.32
Antimuscarinic drugs	Oxybutynin	Bladder antimuscarinic drugs with dementia (S)	1.95	1.90
		Bladder antimuscarinic drugs with chronic glaucoma (S)	1.72	1.74
		Bladder antimuscarinic drugs with chronic constipation (S, B)	2.05	2.00
		Bladder antimuscarinic drugs with chronic prostatism (S)	1.84	1.85
NSAIDs	Indomethacin, Piroxicam, Ketoprofen, Meloxicam	NSAID with a history of peptic ulcer disease or gastrointestinal bleeding, unless with concurrent histamine H_2 receptor antagonist, PPI or misoprostol (S)	1.68	1.68
		Chronic constipation (B)	2.37	2.32
		NSAID with moderate-severe hypertension (moderate: 160/100 mmHg; severe: ≥180/110 mmHg) (S)	2.39	2.42
		NSAID with heart failure (S, B)	1.94	1.94
		Long-term use of NSAID (>3 mo) for relief of mild joint pain in osteoarthtitis (S)	2.06	2.11
		Warfarin & NSAID together (S)	1.74	1.68
		NSAID with chronic renal failure (estimated glomerular filtration rate 20–50 mL/min) (S) Poor kidney function (B)	1.38	1.35
		Long-term NSAID or colchicine for chronic treatment of gout where there is no contraindication to allopurinol (S)	2.13	2.18
Alpha-blockers	Prazosin, doxazosin, terazosin	Alpha-blockers in males with frequent incontinence, i.e., ≥1 episodes of incontinence daily (S)	2.26	2.42
		Stress or mixed urinary incontinence (loss of urine when sneezing/coughing/ bending over/with exercise) (B)	2.05	2.16
		Alpha-blockers with long-term urinary catheter in situ, i.e., >2 mo (S)	2.13	2.19
		Syncope or fainting (B)	1.65	1.50

NSAID = nonsteroidal anti-inflammatory drug; PIM = potentially inappropriate medication; STOPP = Screening Tool for Older Person's Prescriptions.

PIM criteria in Asian countries. The Delphi survey result revealed overall consensus on the PIM criteria which were developed in Western countries. Participants of the survey agreed that all the 26 ingredients for 37 diseases or clinical conditions included in the questionnaires were inappropriate for Korean elderly. Although, Kim et al[17] developed a list of 57 PIM drugs for Korean elderly using the Delphi survey method with a 14 expert panel, they adopted only drug ingredients without considering clinical conditions based on Beers criteria[6,18,19], Canadian criteria[8], and Zhan's classification[20] using Fialova et al's[21] therapeutic classification.

The Delphi survey method has several possible limitations. Firstly, the Delphi method applied as a consensus validation technique in generating PIM list allowed Delphi participants to answer a clear-cut single score to individual questions without considering more complex individualized clinical situations of patients in real practices, resulting in a greater dependence on the 20 Delphi participants' opinions. Accordingly, mean scores towards convergence were used to decide eligibilities of individual criteria. This kind of iterative Delphi procedure has been used frequently in expert consensus validations for developing inappropriate drug lists for elderly in other country settings[6,22–24]. Secondly, 20 experts participated in the Delphi survey were all the professors belonging to medical schools or pharmacy schools. This may arouse concerns about a weak representativeness of the real world of clinical practices. However, our selection was the result of our best-efforts considering their concurrent working practices as

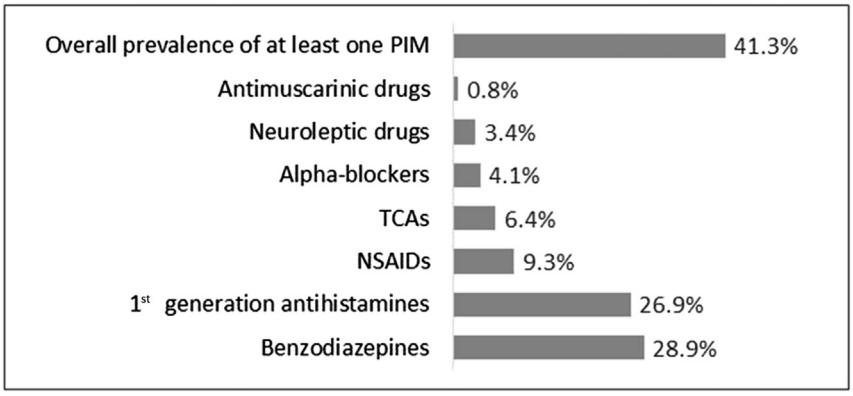

Figure 2. Prevalence rate of potentially inappropriate medication in elderly population who utilized long-term care services during 6 months. NSAIDs = nonsteroidal anti-inflammatory drugs; PIM = potentially inappropriate medication; TCAs = tricyclic antidepressants.

well as their reputations as well-known experts in those fields. Thirdly, questionnaire items included in the Delphi survey were extracted basically from other countries' criteria, which were probably focusing on the drug products being marketed in those countries. It meant that the drug list validated in this study did not fully cover all the drugs available in the Korean drug market. But, there was no available data useful for evidence-based PIM list generation in this study. Thus, consensus validation for currently available criteria, even though they were originated in the other country situations, was practical at this time. Further research is needed to strengthen this study's results through the systematic generation of independent explicit criteria for PIM more suitable for Asian.

4.2. PIM prevalence

An overall PIM prevalence rate of 41.4% in Korean elderly who utilized long-term care services reported in this study seems quite high. Recent studies reported different prevalence rates of at least one PIM in a different country and a different setting. In Italy, the PIM prevalence rate in hospitalized elderly patients according to 2012 version of the Beers' criteria was 23.5%[25]. In Spain, 37.5% of elderly in a primary health care setting used PIM according to original STOPP criteria[26]. In Australia, 40% of patients were exposed to at least one PIM in 2005 according to Beers criteria[27], and in the UK, 26.7% of patients in a hospital setting used PIM according to STOPP criteria[28]. In Brazil, 82.6% among the elderly who used drugs daily were exposed to at least one PIM[29].

There are some limitations in PIM prevalence analysis of this study. Firstly, the NHI claims data we used did not include sufficient information on the clinical conditions of patients, which was necessary to properly evaluate the inappropriateness of medication. For example, we could not identify a specific event (e.g., fall within past 3 months) occurrence date, because the NHI claims data recorded by the ICD-10 code did not include detailed information on patients' clinical conditions. This limitation probably resulted in the overestimation of PIM prevalence, in particular for benzodiazepines, neuroleptics, and first generation antihistamines, due to unclear patient history of falls. In addition, we could not investigate any possible effect of PIM on patient's health outcomes. Secondly, the NHI claims data did not include some drug ingredients which were not reimbursed by the NHI service, even though they are used in the market such as doxepin, oxazepam, and thioridazine, and which were not available in the Korean market, such as trimipramine and zaleplon. This limitation might lead to the underestimation of PIM prevalence rate in Korean elderly. However, the NHI claims data including whole Korean populations are a very worthy source for comprehending the magnitude of PIM exposures under the NHI system. Further research to investigate an association between PIM exposures and clinical outcomes are required to strongly support the usefulness of explicit criteria in clinical practices.

In conclusion, the localized list of PIM criteria generated through an expert consensus validation process in this study may help clinical practitioners choose the optimal drug for their elderly patients. Application of the PIM criteria could reduce drug-related adverse events and prevent subsequent health care costs. Also, it could be used as teaching material for training medical students and practicing doctors to encourage appropriate medication use in caring for elderly patients and a tool for evaluating the quality of drug prescriptions in clinical settings. A high prevalence rate of PIM in the elderly under long-term care services reported in this study suggests necessities of designing efficient strategies for reducing PIMs to assure drug safety together with successful treatment outcomes.

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